Remarks/Arguments

The Office Action dated February 23, 2007 has been received and carefully studied. The Examiner provisionally rejects Claims 1-4 on the ground of nonstatuatory obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 10/500,391. The Examiner states that although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in this application are a broader version of the claims in the copending application.

This provisional rejection is respectfully traversed. Claim 1 in this application requires "first and second drainage paths, wherein said controller directs the flow of said cerebrospinal fluid into said first or second drainage paths in response to the inclination of said individual". However, the claims in the copending application have no such requirement. Those claims require a pressure sensor, an inclination sensor, a wireless transceiver, and an embedded microprocessor. Therefore, the claims in the present application cannot properly be regarded as a broader version of the claims in the copending application.

The Examiner rejects claims 1-11 under 35 U.S.C. §102(b) as being anticipated by Hakim (U.S. Patent No. 3,886,948). This rejection is respectfully traversed.

With respect to claim 1, the Examiner states that Hakim teaches a system for regulating the flow of cerebrospinal fluid (CSF) comprising an implantable controller 60 in the form of a ventricular shunt adapted to be in fluid communication with said CSF and having first and second drainage paths 102/104, and 62, wherein the controller directs the flow of CSF into said first or second drainage

path in response to the inclination of said individual, signaled by contraction of the brain. The Examiner seems to identify chamber 102/drainage catheter 104 as a first drainage path and catheter 62 as a second drainage path. The Examiner cites column 3, lines 57-64 as support for the interpretation of catheter 62 and column 5, line 67 - column 6, line 15 as support for the interpretation of elements 102/104. The Examiner cites no support for the assertion that inclination can be "signaled by contraction of the brain".

This rejection is respectfully traversed. Hakim discloses a shunt "having means to adjust and vary the valve operating pressure with respect to ventricular size such that the proper balance of forces within the cranium may be maintained". Column 2, lines 48-52. Specifically, Hakim varies the pressure required to open the valve based on the ventricular size. Hakim notes that the valve has "a working pressure that varies inversely with the force applied" within the subdural space. Column 3, lines 13-15. There is no reference or suggestion, that ventricular size is in any way related to the inclination of the patient. Furthermore, Hakim does not disclose two drainage paths as required in the present claim. The present invention discloses a first drainage path 27 that is utilized when the patient is in the supine position and a second drainage path 25 when the patient is substantially upright. There are not two independent drainage paths disclosed in Hakim. Looking first at Figure 1, all CSF flows through ventricular catheter 50 into drainage valve 60 and exits through drainage catheter 62. There is no other drainage path available. Rather, the catheter 62 referenced by the Examiner as the second drainage path is in actuality the only drainage path available in the embodiment shown in Figure 1. Also, while the Examiner refers

to controller 60, Figure 1 and the accompanying specification clearly describe that element as a valve having a varying operating pressure. Looking next at Figure 6, a completely different embodiment of the invention of Hakim is shown. In this embodiment, the adjustable drainage valve 60 of Figure 1 is replaced by a resilient chamber 102 having a closed tube 100 and a transverse slit 108, which performs the identical function of varying the operating pressure based on the ventricular size. Similarly drainage catheter 104 replaces drainage catheter 62 shown in Figure 1. In this embodiment, CSF flows through ventricular catheter 50 into resilient chamber 102 with slit 108 and exits through drainage catheter 104. Thus, this figure does not show an additional or second drainage path; rather it represents an alternative embodiment, where both embodiments have only a single drainage path. Hakim does not disclose in these embodiments, or in any of the other embodiments, a CSF drainage system having two drainage paths dependent on the patient's inclination.

The Examiner rejects claim 2 by noting that controller 60 directs the flow of said fluid into said supine flow path 102/104 when said individual's inclination is supine or substantially supine. As stated above, the Examiner is combining two distinct alternative embodiments in creating this rejection. As stated above, controller 60 of Hakim is simply a valve having a variable operating pressure. As such, it cannot direct the flow of CSF into various paths. Furthermore, the supine flow path 102/104 referenced by the Examiner is simply the valve mechanism of the alternative embodiment shown in Figure 6. In other words, valve 60 and resilient chamber 102 do not concurrently exist in any

embodiment; rather they are alternative implementations of the same function.

The Examiner rejects claim 3, stating that second drainage path 62 is an upright flow path. As stated above, there are not two independent flow paths disclosed by Hakim; there are simply multiple embodiments.

The Examiner rejects claim 4, stating that an inclination sensor 24 for sensing the inclination of the individual is shown in Figure 1. Fluid filled bladder 24 is inserted into the subdural region and from that location is able to sense the ventricular size. As stated above, there is no disclosure or suggestion that ventricular size is in any way associated with or dependent on the patient's inclination.

The Examiner rejects claim 5, noting that Hakim discloses a bi-stable latching valve 69 wherein controller 60 directs flow of CSF by actuating latching valve 69 via a hydraulic connection tube 25 to sensor 24 to allow fluid communication with the first or second drainage paths. However, close reading of the specification shows that the reference designator 69 is actually a typographical error; the author was actually describing and referring to valve 60. There is no bi-stable latching valve disclosed by Hakim. Furthermore, as noted above, there are not two separate drainage paths disclosed by Hakim.

The Examiner rejects claim 6 noting that supine path 102/104 comprises a passive low resistance flow path in that it comprises slit 108 which functions as a passive check valve. Again, Hakim does not disclose separate supine and upright flow paths. Furthermore, the slit 108 of Hakim is not a low resistance path. Rather, "sufficient CSF pressure will cause the slit 108 to open and provide drainage". Column 6,

lines 6-7. The requirement that sufficient pressure must exist before the slit opens suggests that it is not a low resistance path.

The Examiner rejects claim 7, stating that since both Hakim and the present application apply to humans, Hakim inherently teaches a maximum intraventricular pressure of about 15 mm Hg. However, the maximum intraventricular pressure as stated in the claim is not an inherent characteristic of a human; rather it is a design characteristic of the CSF flow path system. All flow path systems need not control the intraventricular pressure to the same pressure. As noted by the Examiner, Hakim does not teach a CSF system which maintains a maximum intraventricular pressure of 15 mm Hg. Since the maximum pressure is a design characteristic of the present invention, it cannot be stated that the device of Hakim maintains this same pressure.

The Examiner rejects claim 8, stating that the system of Hakim further comprises a programmable variable check valve as taught by reference to U.S. Patent No. 3,188,142. As stated above, Hakim does not disclose two flow paths, therefore this claim cannot be anticipated by this reference.

The Examiner rejects claims 9, stating that Hakim discloses that the operating pressure is continually modified to maintain a relatively stable pressure for a range of inclination angles. As stated above, Hakim does not disclose any relationship between ventricular size and inclination angle. Thus, Hakim cannot disclose the modification of the operating pressure based on the inclination angle of the patient.

The Examiner rejects claim 10, stating that Hakim discloses that the stable pressure is 3.31. mm Hg. However,

since claim 9 is not anticipated by this reference, claim 10, which depends from claim 9, cannot be anticipated either.

The Examiner rejects claim 11, stating that the controller 60 has an inlet, an outlet, an inlet cannula and an outlet cannula. However, the system of Hakim does not disclose all of the elements recited in claim 1. Therefore, claim 11 cannot be anticipated by this reference.

In summary, Hakim does not disclose the use of two distinct flow paths. Rather, Hakim discloses a variety of alternative embodiments that each can perform the function claimed by Hakim. Furthermore, Hakim does not teach or disclose the use of inclination angle as a way to vary the operating pressure of the valves. Hakim also does not teach or suggest that ventricular size, which his device monitors, is related to inclination angle. Therefore, this reference cannot anticipate the claims of the present application.

Reconsideration and allowance are respectfully requested in view of the foregoing.

Respectfully submitted,

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